



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,520	07/25/2005	Jean-Paul Remon	50304/083001	9447
21559	7590	09/18/2009		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER THEODORE, MAGALI P	
			ART UNIT	PAPER NUMBER
			1791	
			NOTIFICATION DATE	DELIVERY MODE
			09/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No. 10/536,520	Applicant(s) REMON ET AL.	
	Examiner Magali P. Théodore	Art Unit 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-57 and 59-65 is/are pending in the application.
- 4a) Of the above claim(s) 39-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/11/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's remarks filed May 15, 2009 were received.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 51 recites a "drug belonging to Class II or Class IV of the Biopharmaceutical Classification System." That recitation is indefinite because, as new drugs are developed, the contents of Classes II and IV are subject to change. For the sake of compact prosecution, the recitation has been interpreted to mean "a therapeutic agent selected from the following list: beta-blockers, calcium antagonists, ACE inhibitors, sympathomimetic agents, hypoglycemic agents, contraceptives, alpha-blockers, diuretics, anti-hypertensive agents, anti-psoriatics, bronchodilators, cortisones, anti-mycotics, salicylates, cytostatics, antibiotics, virustatics, antihistamines, UV-absorbers, chemotherapeutics, antiseptics, estrogens, scar treatment agents, antifungals, antibacterials, antifolate agents, cardiovascular agents, nutritional agents, antispasmodics, analgesics, antipyretics, anti-inflammatory agents, coronary vasodilators, peripheral vasodilators, antitussive, muscle relaxants, tranquilizers,

Art Unit: 1791

antiarrhythmic agents, anticoagulants, antiemetics, expectorants and antidiabetic agents.”

Claim Rejections - 35 USC § 102/103

Claims 45, 47, 52-53 and 55-56 and 60 are rejected under 35 U.S.C. 102(b) as anticipated by Sugano et al. (US 4,416,606), henceforth **Sugano** or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Sugano** in view of **Martin** (2001).

Regarding **claim 45**, Sugano teaches a continuous wet granulation method (1:5-7) comprising the steps of by feeding a powder (sodium percarbonate, 6:8) to a first transport zone (figure 1 zone I), feeding a liquid (aqueous solution, 6:11) into the same transport zone, continuously advancing the resulting mixture from the transport zone to an agglomeration zone downstream (figure 1 zone II₁), transporting the mixture to a second transport zone further downstream (figure 1 zones II₂ and III) and discharging the resulting granules without submitting them to any pressure gradient (figure 5:8). The zero pressure gradient is inherent to the machine's open design (2:24).

In the alternative, because Martin teaches a zero pressure gradient in the final transport zone of a twin screw extruder (figure 7 left), it would have been obvious to one of ordinary skill in the art to combine the use of zero pressure gradient at the final transport zone with the steps taught by Sugano in order to achieve predictable results with a reasonable expectation of success.

Regarding **claim 47**, Sugano teaches a twin screw (figure 1:2).

Regarding **claim 52**, Sugano teaches that the powder is a chemical (sodium percarbonate, 6:8).

Regarding **claim 53**, Sugano teaches that the weight of the liquid is about 2 % of the weight of the powder (2 liters of aqueous solution per 20 kg of powder equals 1 %, 6:10-13).

Regarding **claims 55-56**, Sugano teaches drying and dry-milling the discharged granules (5:11-16).

Regarding **claim 60**, Sugano teaches avoiding a die or similar device by using a zero pressure gradient. This is explained in the rejection of claim 45.

Claim Rejections - 35 USC § 103

Claims 46, 54 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Sugano** or, in the alternative, **Sugano** in view of **Martin**, as applied to claim 45 above.

Regarding **claim 46**, Sugano does not teach additional agglomeration or transport zones. However, it would have been obvious to one of ordinary skill in the art to duplicate those zones and the corresponding steps in order to effect more agglomeration. It has been held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See MPEPAGE 2144.04 VI B, in re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Regarding **claim 54**, Sugano does not specify an operating temperature. However, Sugano suggests that temperature as a result effective parameter by teaching cooling of the apparatus (4:61-64). Therefore it would have been obvious to one of ordinary skill in the art to optimize the operating temperature because Sugano teaches

Art Unit: 1791

cooling. Optimizing a result-effective parameter known in the art does not impart patentable distinction to an invention. See MPEPAGE 2144.05 [R-5] II, in re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding **claim 59**, Sugano does not teach the claimed liquid to powder ratio. However, this ratio is a result effective parameter because it determines the viscosity and friability of the mixture. If the mixture is too wet, it will not hold its shape; if the mixture is too dry, it will not hold together. Therefore, it would have been obvious to one of ordinary skill in the art to optimize the liquid to powder ratio in the method taught by Sugano in order to control the mixture's viscosity and friability. Optimizing a result-effective parameter known in the art does not impart patentable distinction to an invention. See MPEPAGE 2144.05 [R-5] II, in re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 61-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Sugano** or, in the alternative, **Sugano** in view of **Martin**, as applied to claims 45 and 55 above, and further in view of Gamlen et al. (1986), henceforth **Gamlen**.

Regarding **claims 61-64**, Sugano does not teach making tablets. However, Gamlen teaches making tablets from pharmaceutical granules (tableting, page 1702 line 5). Therefore it would have been obvious to one of ordinary skill in the art to combine the step of making tablets with the steps taught by Sugano in order to achieve predictable results with a reasonable expectation of success.

Regarding **claim 65**, Sugano teaches a continuous wet granulation method (1:5-7) comprising the steps of by feeding a powder (sodium percarbonate, 6:8) to a first transport zone (figure 1 zone I), feeding a liquid (aqueous solution, 6:11) into the same transport zone, continuously advancing the resulting mixture from the transport zone to an agglomeration zone downstream (figure 1 zone II₁), transporting the mixture to a second transport zone further downstream (figure 1 zones II₂ and III) and discharging the resulting granules from the second transport zone through an aperture (figure 2:8).

Sugano's aperture is not collinear with the machine. However, it is the examiner's position that this is an obvious matter of engineering design that would have been obvious to one of ordinary skill in the art to modify. *Alternatively*, Gamlen teaches a discharge aperture (figure 1: "trusion late") collinear to the machine. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the collinear position for the position of Sugano's aperture in order to achieve predictable results with a reasonable expectation of success.

Claims 45-46, 48-54, 57, 59-61 and 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gamlen**, in view of **Sugano** or, in the alternative, **Gamlen** in view of **Sugano** and **Martin**.

Regarding **claim 45**, Gamlen teaches mixing powder and liquid (page 1705) and granulating the mixture to make pharmaceutical pills (page 1702 lines 3-7).

Gamlen's method involves the continuous (introduction, first line) extrusion of the mixture through a perforated plate (page 1705 lines 5-8). However, Sugano teaches

Art Unit: 1791

that extruding the mixture through a perforated plate requires one to constantly replace the clogged plate (1:33-39). Sugano's remedy is a method comprising the steps of by feeding a powder (sodium percarbonate, 6:8) to a first transport zone (figure 1 zone I), feeding a liquid (aqueous solution, 6:11) into the same transport zone, continuously advancing the resulting mixture from the transport zone to an agglomeration zone downstream (figure 1 zone II₁), transporting the mixture to a second transport zone further downstream (figure 1 zones II₂ and III) and discharging the resulting granules without submitting them to any pressure gradient (figure 5:8). The zero pressure gradient is inherent to the machine's open design (2:24). Therefore it would have been obvious to one of ordinary skill in the art to replace the extrusion steps taught by Gamlen with the steps taught by Sugano because Sugano's steps eliminate the problem of the stopped-up extrusion plate.

In the alternative, if it is Applicant's position that the zero pressure gradient is not inherent to Sugano's machine, because Martin teaches a zero pressure gradient in the final transport zone of a twin screw extruder (figure 7 left), it would have been obvious to one of ordinary skill in the art to combine the use of zero pressure gradient at the final transport zone with the steps taught by Sugano in order to achieve predictable results with a reasonable expectation of success.

Regarding **claim 46**, Sugano does not teach additional agglomeration or transport zones. However, it would have been obvious to one of ordinary skill in the art to duplicate those zones and the corresponding steps in order to effect more agglomeration. It has been held that mere duplication of parts has no patentable

Art Unit: 1791

significance unless a new and unexpected result is produced. See MPEPAGE 2144.04 VI B, in re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Regarding **claim 48**, Gamlen does not specify a residence time. However, in any agitation process involving powder and liquid, powder needs time to absorb the liquid. Gamlen suggests that residence time is a result effective variable by proposing it as the object of further study (page 1713, Conclusion, part b). Therefore it would have been obvious to one of ordinary skill in the art to optimize the residence time of the mixture in the machine. Optimizing a result-effective parameter known in the art does not impart patentable distinction to an invention. See MPEPAGE 2144.05 [R-5] II, in re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding **claims 49-52**, Gamlen teaches that the powder is about 80 % paracetamol, an analgesic.

Regarding **claim 53**, Gamlen teaches that the weight of the liquid is about 16 % of the weight of the powder ($15.3 \text{ kg} / 70 \text{ kg} = 25 \%$, page 1705 last two lines -page 1706:1-3).

Regarding **claim 54**, Gamlen does not specify an operating temperature. However, Gamlen suggests that temperature as a result effective parameter by teaching cooling of the mixture throughout the process (page 1705:10). Therefore it would have been obvious to one of ordinary skill in the art to optimize the operating temperature because Gamlen teaches constant cooling. Optimizing a result-effective parameter known in the art does not impart patentable distinction to an invention. See MPEPAGE 2144.05 [R-5] II, in re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Art Unit: 1791

Regarding **claim 57**, Gamlen teaches that the powder includes hydroxypropyl methyl cellulose (abstract line 4, page 1705 formula 2).

Regarding **claim 59**, Gamlen does not teach the claimed liquid to powder ratio. However, this ratio is a result effective parameter because it determines the viscosity and friability of the mixture. If the mixture is too wet, it will not hold its shape; if the mixture is too dry, it will not hold together. Therefore, it would have been obvious to one of ordinary skill in the art to optimize the liquid to powder ratio in the method taught by Gamlen in order to control the mixture's viscosity and friability. Optimizing a result-effective parameter known in the art does not impart patentable distinction to an invention. See MPEPAGE 2144.05 [R-5] II, in re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding **claim 60**, Sugano teaches avoiding a die or similar device by using a zero pressure gradient. This is explained in the rejection of claim 45.

Regarding **claim 61** and **63-64**, Gamlen teaches making tablets (tableting, page 1702 line 5).

Response to Arguments

Applicant's arguments, see Remarks pages 10-11, filed June 11, 2009, with respect to the rejection of claim 51 under 135 USC 112 2nd paragraph because of "poorly soluble" have been fully considered and are persuasive. The part of the rejection based on "poorly soluble" of claim 51 has been withdrawn.

Art Unit: 1791

Applicant's arguments regarding BCS Classes II and IV have been fully considered but they are not persuasive. As stated in the rejection, what is encompassed by Classes II and IV is subject to change as new drugs are developed and classified. Neither the claim in its current form nor the BCS in its current form can anticipate what will fall into those classes in the future.

Applicant's arguments with respect the art rejections have been considered but are moot in view of the new ground(s) of rejection.

Specifically, Sugano's second transport zone has been newly defined to include zone III. Calling zone III a transport zone is justified because granules are not only cut there but also transported rightward from zone II₂ to the aperture (figure 2:8). Therefore, granules are discharged from the second transport zone.

Also, regarding the zero pressure gradient, the examiner has explained why Sugano's second transport zone has a zero pressure gradient and why, in the alternative, it would have been obvious to one in the art to have it.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magali P. Théodore whose telephone number is (571) 270-3960. The examiner can normally be reached on Monday through Friday 9:00 a.m. to 6:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina A. Johnson can be reached on (571) 272-1176. The fax phone

Art Unit: 1791

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Magali P. Théodore/
Examiner, Art Unit 1791

/Joseph S. Del Sole/
Supervisory Patent Examiner, Art Unit 1791